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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,311	07/02/1999	GEERT PLAETINCK	B0192/7010	3674

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EXAMINER

SORBELLO, ELEANOR

ART UNIT PAPER NUMBER

1633

DATE MAILED: 01/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No

09/347,311

Applicant(s)

PLAETINCK ET AL.

Examiner

Eleanor Sorbello

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-21, 23, 24, 38-45, 47, 48 and 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's copy

Response to amendment

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Eleanor Sorbello Group Art Unit 1633.
2. Applicant's amendment and response to the official Office Action mailed 6/21/01, as Paper No. 18, has been received and filed on 11/26/01 as Paper No. 20D. Claims 1,3,7,10, 11, 20 have been amended, and claim 92 has been added. **Claims 1-15, 17-21, 23, 24, 38-45, 47-48, 92 are pending.** Applicant's amendments and arguments have been thoroughly reviewed, but are persuasive only to a point for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's argument.
3. Applicant's arguments are addressed below on a per section basis.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-15, 17-21, 23, 24, 38-45, 47, 48 remain rejected as stated in office action dated 6/21/01, and claim 92 is rejected under 35 USC § 112, first paragraph, because the specification, while being enabling for the use of plasmid vectors that initiate transcription of double stranded RNA introduced into C.elegans, does not

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reasonably provide enablement for all other limitations encompassed by the claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments have been fully considered but they are not persuasive.

Applicants argue that they have amended the claims to nematodes and that one of skill in the art will not require undue experimentation to practice the claimed invention. However the examiner argues that the claim still encompasses any and all multicellular organisms for which applicants are not enabled for in vivo applications.

Applicants argue that the specification teaches vectors that initiate transcription of a cDNA or DNA to double stranded RNA and therefore should be enabled for any vector system. However, examiner argues that the claims are not limited to nematodes and the transcription of RNA, but the claims encompass DNA delivery, transcription and expression in any multicellular organism for which applicants are not enabled.

Applicants argue that the examiners statement regarding the fact that the mechanism of RNA interference was not known and unpredictable at the time of filing of the instant application, (because the reason why dsRNA had greatly enhanced interference as compared to ssRNA was not known), but which was not relevant to that which is claimed. Examiner agrees.

Regarding the generation of cDNA libraries applicants argue that it is routine in the art and that the vector chosen is a matter of choice. Examiner agrees. However it is not clear to the examiner how an entire cDNA library representing all the genes that

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encode proteins in *C. elegans* is to be introduced into one (or more) nematode cells, as claimed in claim 1 (b), so as to be able to identify only one phenotype.

Therefore in view of the nature of the invention, state of the art, breadth of the claims and guidance in the specification one of skill in the art will require undue experimentation to make and use the invention as claimed.

Conclusion

6. Claims 1-15, 17-21, 23, 24, 38-45, 47, 48, 92 are rejected.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER